

IN THE SPECIFICATION:

Please amend page 1, line 10-12 of the specification to read as follows: "This application is a divisional of Application No. 09/071,710, filed May 1, 1998, now U.S. Patent 6,130,043, which is a continuation-in-part of U.S. application Serial No. 08/850,713 filed May 2, 1997, now abandoned, from which priority is claimed pursuant to 35 U.S.C. Section 120 and which is incorporated herein by reference in its entirety."

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REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested.

Claims 38 and 39 have been amended. No new matter has been added as a result of these amendments.

Priority

The Examiner indicated that the present application lacked the necessary reference to the prior application. Applicants thank the Examiner for pointing this out. The specification, on page 1, lines 10-12 has been amended to include such a reference.

Claim Rejections – 35 U.S.C. Section 112, First Paragraph

Claims 10-16, 33, 35, 38 and 39 are rejected under 35 U.S.C. Section 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. According to the Examiner, the current claims encompass a genus of nucleic acids that are different than those disclosed in the specification.

The Examiner states that the genus includes variants for which no written description is provided in the specification. Applicants respectfully traverse this rejection.

The inquiry into whether the description requirement is met is determined on a case-by-case basis and is a question of fact. *Manual of Patent Examining Procedure*, Section 2163.04 (8th Edition, August 2001). When a question regarding the adequacy of the written description arises, the fundamental factual inquiry is whether the specification conveys to those skilled in the art, as of the filing date sought, that Applicant was in possession of the invention being claimed. *Manual of Patent Examining Procedure*, Section 2163.02 (8th Edition, August 2001). Possession can be shown in a number of ways. For example, an Applicant can show possession by: (1) an actual reduction to practice of the claimed invention; (2) a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention; or (3) any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Manual of Patent Examining Procedure*, Section 2163 (8th Edition, August 2001).

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the Examiner to rebut the presumption. *Manual of Patent Examining Procedure*, Section 2163.04 (8th Edition, August 2001). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. *Id.* The Examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicants disclosure a description of the invention as defined by the claims. *Id.*

Applicants respectfully submit that the specification as filed is adequate and reasonably conveys to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. More specifically, with respect to the “50% identity”

language, the specification specifically describes how “% identity” (see page 11, lines 30-35 and page 12, lines 1-5) can be determined using various programs known in the art, including the Wisconsin Sequence Analysis Package 8. Applicants herewith enclose the software manual to the Wisconsin Sequence Analysis program, Version 8, which is publicly available from Genetics Computer Group, Madison Wisconsin, as Exhibit A. Support for this submission is found on page 11, line 35 – page 12, line 1. This manual provides the algorithm, parameters, parameter values and other information necessary to, accurately and consistently, calculate the percent identity. This manual indicates on pages 5-21, *inter alia*, that the software used the local homology algorithm of Smith and Waterman (*Advances in Applied Mathematics* 2:482-489 (1981)). Applicants submit that using the information provided in the specification along with the publicly available software manual that is supplied with the Wisconsin Sequence Analysis program, one skilled in the art would readily be able to discern the nucleic acids encompassed by the scope of the claims and that the inventors were in possession of the claimed invention at the time of filing. Thereupon, Applicants submit that this rejection should be withdrawn.

Rejection of Claims 38 and 39 under 35 U.S.C. Section 112, Second Paragraph

Claims 38 and 39 are rejected under 35 U.S.C. Section 112, Second Paragraph as being indefinite. Specifically, the Examiner stated that the language “gene or fragment thereof” was vague and indefinite. Claims 38 and 39 have been amended to remove this language. Thereupon, in view of these amendments, Applicants submit that this rejection has now been rendered moot and should be withdrawn.

Rejection of Claims 10-16, 30, 33, 35, 38 and 39 Under 35 U.S.C. Section 102(b)

Claims 10-16, 30, 33, 35, 38 and 39 have been rejected under 35 U.S.C. Section 102(b) as being anticipated by de Louvencourt et al. (U.S. Patent 4,806,472). Applicants respectfully traverse this rejection.

In his rejection, the Examiner states that "there is no minimum size limitation on the fragment of claim 10, so a fragment of only three nucleotides can potentially constitute an ORF, since many triplets can encode an amino acid." Applicants submit that this is not accurate and respectfully direct the Examiner's attention to the definition of the term "fragment" on page 13 of the specification. As defined by the specification, a "fragment" of a specified polynucleotide "refers to a polynucleotide sequence which comprises a contiguous sequence of approximately at least about 6 nucleotides, preferably at least about 8 nucleotides, more preferably at least about 10-12 nucleotides, and even more preferably at least 15-20 nucleotides corresponding, i.e., identical or complementary to, a region of the specified nucleotide sequence."

The Examiner refers to the EcoR1 site that comprises GAA and that GAA is a fragment found in SEQ ID NO:2. The sequence GAA contains less than six (6) nucleotides and hence is not a fragment as defined by Applicants specification.

Therefore, because each and every element of the claimed invention is not found in de Louvencourt et al. (U.S. Patent 4,806,472), Applicants submit that this rejection has now been rendered moot and should be withdrawn.

Rejection of Claims 10-14, 33, 38 or 39 Under 35 U.S.C. Section 103(a)

Claims 10-14, 33, 38 and 39 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Southern (U.S. Patent 6,054,270). Applicants respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, the Examiner must establish three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings (*Manual of Patent Examining Procedure* Section 2142 (8th Edition, August 2001)). Second, there must be a reasonable expectation of success. *Id.*

Finally, the prior art references must teach or suggest all the claim limitations. *Id.* In view of these criteria, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness.

The Examiner argues that Southern teaches hybridization of 8-mers to the array to yield double stranded molecules. According to the Examiner, these arrays would inherently and necessarily comprise every 8 mer fragment of SEQ ID NOS 1-16.

Applicants submit that the prior art cited by the Examiner fails to teach or suggest all of the claim limitations. Southern does not teach any of the sequences of the present invention or fragments thereof. Rather, the Examiner speculates that the arrays of Southern would “inherently and necessarily” comprise every 8 mer fragment of SEQ ID NOS 1-16.” The Examiner has not provided any evidence to support his argument that such 8 mer fragments would be inherently disclosed by Southern.

Finally, Applicants wish to advise the Examiner that all of the pending claims are commonly owned.

Therefore, in view of the aforementioned arguments, Applicants submit that the rejection of claims 10-14, 33, 38 and 39 under 35 U.S.C. Section 103(a) as being unpatentable over Southern should be withdrawn.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If any additional fees

are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account No. 01-0025.



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A handwritten signature of Mimi C. Goller is written over her name and professional information.

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Version Showing Changes Made

Please amend claims 38 and 39 as follows:

38. (Amended). A [gene, or fragment thereof, which] polynucleotide that codes for a PS108 protein [which] compris[es]ing an amino acid sequence having at least 50% identity to SEQUENCE ID NO 36.

39. (Amended). A [gene, or fragment thereof,] polynucleotide comprising DNA having at least 50% identity with SEQUENCE ID NO 15 or SEQUENCE ID NO 16.